K013894

JAN 18 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

General information

Company Name	:	Philips Medical Systems North America Company.
Address	:	22100 Bothell Everett Highway P.O. Box 3003
Registration No.	:	Bothell, WA 98041-3003
Contact person	:	Lynn Harmer
Device (Trade) Name	:	**Transmit/Receive Quadrature Body Coil 3.0T.**
Classification Name	:	Magnetic Resonance Diagnostic Device (MRDD).
Classification	:	Class II.
Product code	:	MOS
Performance standards	:	NEMA voluntary standards, FDA MRDD guidance's, UL and IEC 601 appropriate safety standards and/or draft standards are used.
Common/Usual Name	:	Transmit/Receive Quadrature Body Coil 3.0T

Predicate Device(s):

The **Transmit/Receive Quadrature Body Coil 3.0T** is an extension to the MRDD Philips INTERA 3.0T System (re K003516). The **Transmit/Receive Quadrature Body Coil 3.0T** is equivalent to Quadrature Body Coil used with the INTERA 1.5T system.

Indications for use:

The indication for use for the **Transmit/Receive Quadrature Body Coil 3.0T** expands the INTERA 3.0T system capability as a diagnostic device that produces transverse, sagittal, coronal and oblique cross-sectional images based upon ^{1}H metabolites, and that displays the internal structure of the whole body.These images when interpreted by a trained physician, yield information that may assist in diagnosis

Device description:

The Transmit/Receive Quadrature Body Coil 3.0T is a bird-cage type transmit/receive coil designed for use in the Intera 3.0T system. In transmit mode the coil is used in almost every kind of scan. In receive mode the coil is mainly used for imaging with a large field of view. The QBC has a fixed position inside the gradient coil .

General Safety and Effectiveness.

The safety of the INTERA 3.0T system with the Transmit/Receive Quadrature Body Coil 3.0T remain the same as with the FDA cleared INTERA 1.5T (re. K001796).The Transmit/Receive Quadrature Body Coil 3.0T permits the INTERA 3.0T system to be used as a whole body scanner. It was distributed as a head scanner only. The QBC 3.0T does not result in any new potential hazard.

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Substantial Equivalence.

It is the opinion of Philips Medical Systems that the **Transmit/Receive Quadrature Body Coil 3.0T** is substantially equivalent to its predicate device quadrature body coil used in the INTERA 1.5T (re.K001796)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2002

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

Re: K013894
Trade/Device Name: Transmit/Receive Quadrature Body Coil 3.0T System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: November 21, 2001
Received: November 23, 2001

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013894

Device Name : **Transmit/Receive Quadrature Body Coil 3.0T**

Indication For Use :

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013894